

JUN - 6 2003

K031573

3.0 510(k) Summary

Sponsor: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Bonnie Smith

Device Name: Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate

Classification: Class II, § 888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Predicate Device: Synthes 3.5 mm LCP Reconstruction Plate

Device Description: Synthes 3.5 mm Low Profile Pelvic Reconstruction Plates consist of curved plates and straight plates that are contourable in three planes. The plates have a smooth, rounded profile. Plate holes are slightly oval, allowing 30 degrees of angulation in all directions. The 3.5 mm Low Profile Reconstruction Plate accepts Synthes 3.5 mm Cortex Screws and Synthes 3.5 mm Pelvic Screws.

Intended Use: Synthes 3.5 Low Profile Pelvic Reconstruction Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.

Materials: Stainless steel

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 6 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301

Re: K031573

Trade/Device Name: Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, HRS
Dated: May 14, 2003
Received: May 20, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

2.0 Indications for Use Statement

Page 1 of 1

510(k) Number (if known): _____

Device Name: Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate

INDICATIONS: Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K031573

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____